

REMARKS

Applicants have carefully reviewed the Final Office Action mailed June 4, 2007, prior to preparing this paper. Currently, claims 1-16 and 20-45 are pending in the application, wherein claims 1-16 and 20-45 have been rejected. Claims 1, 20, 36, 37, 39, 44 and 45 have been amended, and claims 2-4, 21-23 and 42-43 have been cancelled. Support for the amendments may be found, for example, at lines 6-16 of page 4 of the Specification. No new matter has been added. Favorable consideration of the following remarks is respectfully requested.

Claims 1, 36, 37, 39 and 40 stand rejected under 35 U.S.C. §102(e) as being anticipated by Zhou, U.S. Pat. App. Pub. No. 2002/0183654. Applicants respectfully traverse this rejection.

Each of claims 1, 36 and 39 has been amended to recite that the polymer jacket is in continuous contact with the core wire along a majority of the length of the polymer jacket. Zhou does not teach at least this limitation of the rejected claims. Namely, as disclosed in Zhou, the first tip member (126) must be spaced away from the second tip member (128) in order to allow deflection of the first tip member (126) prior to engaging the second tip member (128). As shown throughout the figures of Zhou, the second tip member (128) only contacts the first tip member (126) at the extreme proximal end of the second tip member (128) and at the extreme distal end of the second tip member (128) when the first tip member (126) is sufficiently deflected. (See FIGS. 4 and 5). Thus, it can be seen that the second tip member (128) is not in continuous contact with the first tip member (126) throughout a majority of the length of the second tip member (128).

For at least this reason, claims 1, 36 and 39 are believed patentable over Zhou. Claims 37 and 40, which depend from one of claims 1, 36 and 39 and contain additional limitations, are similarly believed patentable over Zhou. Withdrawal of the rejection is respectfully requested.

Claims 5-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Zhou, U.S. Pat. App. Pub. No. 2002/0183654, in view of Takahashi, U.S. Patent No. 6,485,458. Applicants respectfully traverse this rejection. Zhou, which has a filing date of May 30, 2001 and a publication date of December 5, 2002 is available as prior art to the current application, if at all, under §102(e). However, §103(c) applies in this instance to remove the reference as prior art against the current application under 35 U.S.C. §103(a). See M.P.E.P. §2136.01. Both Zhou and the current application were subject to an obligation of assignment to the same entity at the

time the invention was made. The Zhou assignment to SciMed Life Systems, Inc. can be found at Reel 011879, Frame 0395 and the assignment of the current application to SciMed Life Systems, Inc. can be found at Reel 012397, Frame 0974 (A corrective assignment correcting the last name of the second conveying party recorded at 012397/0974 can be found at Reel 012870, Frame 0101). Therefore, Zhou is disqualified as prior art in formulating the obviousness rejection under the provisions of §103(c). Withdrawal of the rejection is respectfully requested.

Claims 1-5, 20-24 and 36-45 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Burmeister et al., U.S. Patent No. 5,452,726, in view of Schroepel, U.S. Patent No. 6,024,764. Applicants respectfully traverse this rejection. A *prima facie* case of obviousness has not been made at least because all the claim elements are not taught or suggested by the cited prior art and the proposed modification is not a predictable product of the teachings of the prior art sufficient to maintain an obviousness rejection in view of the Supreme Court's ruling in *KSR International v. Teleflex Inc.*

Claim 1, for example, recites "the polymer jacket being more stiff than the portion of the core wire which it surrounds" and that "the portion of the core wire surrounded by the polymer jacket is bent into a curved shape, wherein the polymer jacket overcomes biasing forces imposed by the elongate core wire which tend to straighten the core wire from the curved shape such that the stiffness of the polymer jacket retains the elongate core wire in the curved shape."

Burmeister teaches a guidewire with a selectively formable metallic core and a plastic jacket enclosing the core. In Burmeister, the core wire is at least in part selectively formable to impart a shape to the wire, which suggests that the core wire is stiffer than the surrounding jacket. See Burmeister at column 5, lines 19-45. It is the use of a shapeable metal such as stainless steel for the core wire which allows the guidewire to be selectively formable. Burmeister states that "By a selectively formable core, it is meant that the wire from which the core is made may be bent to a particular shape and that the shape will be maintained by the wire." Burmeister at column 5, lines 20-23 (emphasis added). Furthermore, Burmeister expressly teaches that:

Superelastic materials, like nitinol, are so resilient that they tend to spring back to their original shape even if bent, thus are not formable. Although superelastic material may be provided with a "preformed" memory shape, such a preformed shape is typically determined in the manufacture of the guide wire and cannot readily be altered or modified by the physician by simply bending the

guide wire prior to use. Although use of superelastic materials such as nitinol in guide wire applications may provide some advantages in certain uses, a formable core, such as of stainless steel, which can be formed by the physician to a shape suitable for a particular patient or preferred by that physician, provides an advantage that cannot be obtained with a superelastic core guide wire.

Burmeister at column 5, lines 32-45. Thus, Burmeister expressly teaches to one of skill in the art that if it is desired to provide a shapeable guidewire, then the core wire should be made from stainless steel, since a shapeable guidewire cannot be obtained with a superelastic core wire.

Schroepfel teaches a tubular sleeve (12) for imparting a preselected shape in an implantable tubular device (10) where the tubular sleeve (12) may be made from a heat sensitive shape memory polymer. The Examiner opines that "it would have been obvious to one having ordinary skill in the art to modify the polymer jacket as disclosed by Burmeister et al. to include a shape memory polymer as taught by Schroepfel so the device can be shaped by a surgeon into a shape and subsequently reshaped if desired to allow for introduction into the patient's anatomy." Applicants respectfully disagree with this stated suggestion.

Schroepfel is silent regarding the material of the implantable tubular device (10), and does not teach that the implantable tubular device (10) is formed of a superelastic metal alloy. As shown in FIG. 2 of Schroepfel and described at lines 27-31 of column 4, Schroepfel teaches a plurality of barbs (24) on the tubular sleeve (12) "penetrate slightly into the exterior surface of the implantable tubular device (10)," thus seemingly negating any suggestion that Schroepfel teaches that the implantable tubular device (10) may be metallic. Schroepfel does not teach one of skill in the art that the tubular sleeve (12) is of a sufficient stiffness to overcome the resilient forces imparted when a superelastic wire is bent.

Thus, the teachings of Schroepfel are not sufficient to negate Burmeister's teaching that a superelastic material would not be used in forming a selectively formable guidewire due to the resiliency of the superelastic material which makes the core wire non-formable. There is no indication or expectation in the prior art that modifying the polymer jacket of Burmeister with a shape memory polymer would be sufficient to make a non-shapeable superelastic guidewire selectively shapeable by a user. The Examiner has failed to provide a finding that one of skill in the art would have combined the teachings of Schroepfel with those of Burmeister, and that one of skill in the art would have predicted that the guidewire, as modified, would have functioned as currently claimed.

For this reason, it would not be obvious for one of skill in the art to modify the polymer jacket as disclosed by Burmeister to include a shape memory polymer as taught by Schroepfel, as it would not have been predictable that the inclusion of the shape memory polymer would be sufficient to overcome the resiliency of a superelastic core wire to spring back to an original straight shape.

Applicants therefore submit that claim 1 is in condition for allowance. As claims 5 and 37 depend from claim 1 and contain additional elements, Applicants submit that these claims are in condition for allowance as well.

Claim 20 recites that the polymer jacket of the guidewire is more stiff than the distal tip portion of the core wire, and "the stiffness of the polymer jacket retains the shape imparted on the distal tip portion of the elongate core wire."

As discussed above, Burmeister expressly teaches to one of skill in the art that a shapeable guidewire cannot be obtained with a superelastic core wire as the resiliency of the superelastic material would not permit the guidewire to be shaped. Furthermore, Schroepfel does not teach one of skill in the art that the tubular sleeve (12) is of a sufficient stiffness to overcome the resilient forces imparted when a superelastic wire is bent.

Thus, the teachings of Schroepfel are not sufficient to negate Burmeister's teaching that a superelastic material would not be used in forming a selectively formable guidewire due to the resiliency of the superelastic material which makes the core wire non-formable. For this reason, it would not be obvious for one of skill in the art to modify the polymer jacket as disclosed by Burmeister to include a shape memory polymer as taught by Schroepfel, as it would not have been predictable that the inclusion of the shape memory polymer would be sufficient to overcome the resiliency of a superelastic core wire to spring back to an original straight shape.

Applicants therefore submit that claim 20 is in condition for allowance. As claims 24 and 38 depend from claim 20 and contain additional elements, Applicants submit that these claims are in condition for allowance as well.

Each of claim 36 and 39 recites "the polymer jacket being more stiff than the portion of the core wire which it surrounds" and that "the portion of the core wire surrounded by the polymer jacket is bent into a curved shape, wherein the polymer jacket overcomes biasing forces imposed by the elongate core wire which tend to straighten the core wire from the curved shape such that the stiffness of the polymer jacket retains the elongate core wire in the curved shape."

As discussed above, Burmeister expressly teaches to one of skill in the art that a shapeable guidewire cannot be obtained with a superelastic core wire as the resiliency of the superelastic material would not permit the guidewire to be shaped. Furthermore, Schroepfel does not teach one of skill in the art that the tubular sleeve (12) is of a sufficient stiffness to overcome the resilient forces imparted when a superelastic wire is bent.

Thus, the teachings of Schroepfel are not sufficient to negate Burmeister's teaching that a superelastic material would not be used in forming a selectively formable guidewire due to the resiliency of the superelastic material which makes the core wire non-formable. For this reason, it would not be obvious for one of skill in the art to modify the polymer jacket as disclosed by Burmeister to include a shape memory polymer as taught by Schroepfel, as it would not have been predictable that the inclusion of the shape memory polymer would be sufficient to overcome the resiliency of a superelastic core wire to spring back to an original straight shape.

Applicants therefore submit that claims 36 and 39 are in condition for allowance. As claims 40, 41 and 44 depend from claim 39 and contain additional elements, Applicants submit that these claims are in condition for allowance as well.

Claim 45 recites that at least the distal portion of the elongate core wire is formed of a super elastic metal having an elastic limit and having a resiliency to being substantially straight, and that the stiffness of the shape memory polymer jacket overcomes the resiliency of the core wire in order to retain the shape imparted on the distal portion of the elongate core wire.

As discussed above, Burmeister expressly teaches to one of skill in the art that a shapeable guidewire cannot be obtained with a superelastic core wire as the resiliency of the superelastic material would not permit the guidewire to be shaped. Furthermore, Schroepfel does not teach one of skill in the art that the tubular sleeve (12) is of a sufficient stiffness to overcome the resilient forces imparted when a superelastic wire is bent.

Thus, the teachings of Schroepfel are not sufficient to negate Burmeister's teaching that a superelastic material would not be used in forming a selectively formable guidewire due to the resiliency of the superelastic material which makes the core wire non-formable. For this reason, it would not be obvious for one of skill in the art to modify the polymer jacket as disclosed by Burmeister to include a shape memory polymer as taught by Schroepfel, as it would not have been predictable that the inclusion of the shape memory polymer would be sufficient to

overcome the resiliency of a superelastic core wire to spring back to an original straight shape. Applicants therefore submit that claim 45 is in condition for allowance.

Claims 6-16 and 25-35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Burmeister et al., U.S. Patent No. 5,452,726, in view of Schroepfel, U.S. Patent No. 6,024,764, and further in view of Takahashi, U.S. Patent No. 6,485,458. Applicants respectfully traverse this rejection.

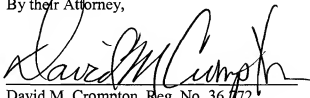
As discussed above, the teachings of Burmeister in view of Schroepfel do not render the subject matter of claims 1 or 20 obvious, from which these claims depend. Takahashi does not remedy the deficiencies of Burmeister and Schroepfel. Therefore, because claims 6-16 and 25-35 depend from one of claims 1 or 20, which Applicants submit are allowable, and contain additional elements, Applicants submit that claims 6-16 and 25-35 are in condition for allowance as well.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,



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